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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,120	12/07/2001	Yoshihiro Kurano	0760-0299P	2911

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EXAMINER

SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 11/28/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/005,120

Applicant(s)

KURANO ET AL.

Examiner

Rodney P. Swartz, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☒ Claim(s) 4 and 10 is/are objected to.
- 8) ☒ Claim(s) 1-17 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3,9,10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' Response to Restriction Requirement, received 30 September 2003, paper #12, is acknowledged.

Applicants elect, without traverse, Invention I, claims 1-16, drawn to antibody, classified in class 424, subclass 130.1. Claim 17 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

2. Claims 1-16 are under consideration.

Priority

3. Acknowledgment is made of applicant's claim for foreign priority based on 2000-374145 filed in Japan on 8 December 2000. It is noted, however, that applicant has not filed a certified English translation of the application as delineated in 35 U.S.C. 119(b). Until a certified English translation of the application is submitted, the priority date is that of the instant application, i.e., 7 December 2001.

In addition, the claim of priority of the Japanese application should be listed in the first paragraph of the specification.

Specification

4. The disclosure is objected to because of the following informalities:

Page 1, line 14, what is meant by "almost localized in nerve system, and progressively aggravate",

Page 2, lines 17 and 19, "antigenecity" should be "antigenicity"; line 20, what is meant by "demanded",

Page 3, line 11, "Because of these" appears to be incomplete,

Page 4, line 11, it is unclear what is meant by "regions are discontinuous each other",

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Page 5, line 6, "reacts" should be "react",

Page 6, line 11, "means fragment" should be "means a fragment",

Page 7, line 12, it is unclear what is meant by "the present inventors thought a structure"; in lines 17, 18, and 21, what is meant by "helix 2" and "helix 3",

Page 8, line 10, what constitutes "E3 region",

Page 9, line 6, "antigenecity" should be "antigenicity"; line 15, "does" should be "do",

Page 13, line 22, if "ABC reagent" is a registered Trademark, it should be so noted; in addition, the company name and address should be included,

Page 20, line 9, "discontinuous each other" is unclear,

Appropriate correction is required.

Claim Objections

5. Claim 4 is objected to because of the following informalities: line 3, "and" should be "an". Appropriate correction is required.

6. Claim 10 is objected to because of the following informalities: line 5, "discontinuous each other in primary" should be "discontinuous **with** each other in **the** primary"; line 7, "ligated each other" should be "ligated **to** each other" Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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9. Claim 6 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what new criticality is added by the language of the dependent claim 6. The claim recites "The monoclonal antibody according to claim 1 or 5 which is a monoclonal antibody."

Claim 9 depends from claim 6, but does not clarify the indefiniteness.

10. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to a method for "measuring" abnormal type prion in an immunoassay utilizing the monoclonal antibody or binding fragment thereof of claim 1 or 5. It is unclear what is meant by "measuring". The specification recites that "measuring" means both identification and quantitation of abnormal type prion. It is recommended that the claim utilize the terms put forth in the specification, i.e., replace "measuring" with "identifying and quantifying".

11. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim improperly appears to be redefining the meaning of the immunogen of claim 10. Claim 10 states that the immunogen includes a peptide while claim 11 states that the immunogen comprises a carrier and said peptide immobilized on said carrier. It is recommended that claim 11 be amended to recite "said immunogen **further** comprises"

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12. Claim 12-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim 12 improperly appears to be redefining the meaning of the immunogen of claim 11. Claim 11 states that the immunogen comprises a carrier and said peptide of claim 10 immobilized on said carrier. Claim 12 states that the immunogen comprises said carrier and "a plurality of kinds of said peptide". It is recommended that claim 12 be amended to recite "said immunogen **further** comprises"

Claim 12 is also indefinite for "plurality of kinds" of said peptide. The specification does not appear to define the scope of the phrase "plurality of kinds".

Claims 13-15 depend from claim 12, but fail to correct the deficiencies.

13. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites "said peptide has **an** amino acid sequence shown in SEQ ID NO:1." This language is indefinite because it is unclear whether the peptide comprises a subsequence of SEQ ID NO:1, or the entire SEQ ID NO:1. It is recommended that the claim read "said peptide comprises the amino acid sequence shown in SEQ ID NO:1."

14. Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to a monoclonal antibody which "reacts" with abnormal type prion but does not substantially "react" with normal type prion. The terminology "reacts" is indefinite.

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It is recommended that the word be replaced with "binds" because this is the activity taught in the specification.

15. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites "pretreatment". However, the scope of what constitutes a pretreatment is unclear. The only example of pretreating prion samples is an acid-autoclaving method.

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

17. Claims 1-3 and 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Prusiner et al (U.S. Pat. No. 5,846,533).

The claims are drawn to a monoclonal antibody which binds with abnormal type prion but does not substantially bind with normal type prion.

Prusiner et al teach a monoclonal antibody which specifically binds *in situ* with abnormal prion, i.e., PrP^{Sc}, but not to normal prion, i.e., PrP^C (Abstract; Examples 16-18).

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Prusiner et al (U.S. Pat. No. 5,846,533).

The claim is drawn to an immunoassay kit for measuring abnormal prion, wherein said kit comprises a monoclonal antibody which binds with abnormal type prion but does not substantially bind with normal type prion.

Prusiner et al teach a monoclonal antibody which specifically binds *in situ* with abnormal prion, i.e., PrP^{Sc}, but not to normal prion, i.e., PrP^C (Abstract; Examples 16-18) and immunoassays for detecting the abnormal prion (Examples 3, 5, 7, and 8). It would have been obvious at the time the invention was made to a person having ordinary skill in the art to package all of the necessary reagents for the immunoassay taught by Prusiner et al in a convenient form.

Conclusion

20. No claims are allowed.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703) 872-9306

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-2035.



RODNEY P. SWARTZ, PH.D.
PRIMARY EXAMINER

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November 20, 2003